



DEPARTMENT OF HEALTH & HUMAN SERVICES

14F E-35
Public Health Service
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FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

July 2, 1997

WARNING LETTER
SJN-97-20

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Angel Guerrero
Supervisor of Marine Operations
Puerto Rico Ports Authority
P.O. Box 362829
San Juan, Puerto Rico 00936-2829

Dear Mr. Guerrero:

During inspection of ship watering points at Pier 1, San Juan, Puerto Rico, conducted on May 28-June 4, 1997 and on a follow up inspection conducted on July 1, 1997, our inspectors found deficiencies which are considered violations of the Public Health Service Act and the Interstate Conveyance Sanitation Regulations; Title 21, Code of Federal Regulations, 1240.83 (21 CFR 1240.83) and 1250.67 (21 CFR 1250.67).

Observations included, but were not limited to, the following deviations:

1. Inadequate design and installation of the six (6) water hydrants in that there exists a dead leg between the control valve installed on the by-pass and the hydrants' outlets. The current plumbing arrangement could allow for the potential of contamination of the water system with stagnant water contained in this dead leg when the system is not properly flushed.

As corrective action, we recommend elimination of the by-pass. A less desirable alternative would be the establishment of a written procedure requiring flushing of this portion of the plumbing system in every one of the six (6) hydrants at a frequency of not less than once every two weeks. This alternative would require that a written log be available for review by the FDA.

2. The six (6) water hydrants are not equipped with an adequate backflow prevention device (the existing device is a single check valve). We enclose a list of alternative devices considered to be adequate for use in potable water supply systems.
3. Hydrants #1 west side and #5 east side were leaking from the outlet.

Mr. Angel Guerrero
July 1, 1997

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The Inspectional Observations, as listed on Forms FDA-483, issued 5/28/97, 6/4/97, and 7/1/97 were discussed with you on the dates they were issued. Copies of the FDA-483s are included for your review.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each applicable requirement of the Public Health Service Act and applicable regulations.

As a result of these observations, the watering points at Pier 1 are classified "Provisional" for servicing interstate carriers. A re-inspection to verify accomplishment of corrective actions will be scheduled as soon as you notify this office in writing of their completion.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

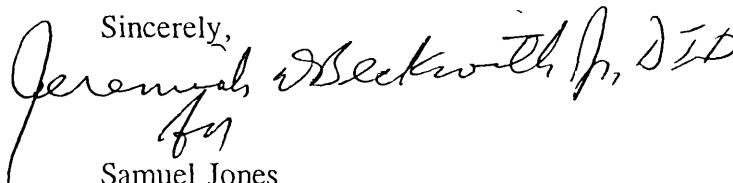
We acknowledge that some corrective actions have been implemented concerning the observations noted on the 5/28/97 inspection. These corrections should also be addressed in your response to this letter.

Your reply should be sent to the Food and Drug Administration, 466 Fernandez Juncos Avenue, Puerta de Tierra, San Juan, Puerto Rico 00901-3223.

If you require any assistance in understanding the contents of this letter, or if you desire a meeting with members of our staff, please contact Acting Compliance Officer Maridalia Torres at (787) 729-6894.

A copy of this letter is being forwarded to the agent for any interstate carrier identified as being serviced at these watering points.

Sincerely,

A handwritten signature in dark ink, appearing to read "Samuel Jones". The signature is fluid and cursive, with a large initial "S" and "J".

Samuel Jones
District Director

Enclosure